



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1030]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Allergen Labeling and Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0792. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Allergen Labeling and Reporting

This information collection supports the reporting associated with the submission of petitions and notifications seeking exemptions from the labeling requirements for ingredients derived from major food allergens, and the Agency's associated guidance document.

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Title II, Pub. L. 108-282) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by defining the term "major food allergen" and stating that foods regulated under the FD&C Act are misbranded unless they declare the presence of each major food allergen on the product label using the name of the food source from which the major food allergen is derived. Section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)) sets forth the requirements for declaring the presence of each major food allergen on the product label. Section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)) defines a major food allergen as "[m]ilk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans" and also as a food ingredient that contains protein derived from such foods. The definition excludes any highly refined oil derived from a major food allergen and any ingredient derived from such highly refined oil.

In some cases, the production of an ingredient derived from a major food allergen may alter or eliminate the allergenic proteins in that derived ingredient to such an extent that it does not contain allergenic protein. In addition, a major food allergen may be used as an ingredient or as a component of an ingredient such that the level of allergenic protein in finished food products does not cause an allergic response that poses a risk to human health. Therefore, FALCPA provides two mechanisms through which such ingredients may become exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient "does not cause an allergic response that poses a risk to human health" (section 403(w)(6) of the FD&C Act). Alternately, an ingredient may become exempt through

submission of a notification containing scientific evidence showing that the ingredient “does not contain allergenic protein” or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act (21 U.S.C. 348) that the ingredient “does not cause an allergic response that poses a risk to human health” (section 403(w)(7) of the FD&C Act).

Description of Respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States that declare the presence of a major food allergen on the product label. In terms of reporting, the respondents are manufacturers and packers of packaged foods sold in the United States that seek an exemption from the labeling requirements of section 403(w)(1) of the FD&C Act.

In the *Federal Register* of October 28, 2020 (85 FR 68333), we published a 60-day notice requesting public comment on the proposed collection of information. Although some comments were received, they pertained to substantive and/or technical aspects of statutory requirements found in section 403(w) of the FD&C Act, or recommendations found in related Agency guidance. None of the comments discussed the information collection topics found in 5 CFR 1320.5(a)(1)(B) as requested in the notice, nor did any of the comments suggest FDA revise its estimate of the burden for the information collection.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden¹

FD&C Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
403(w)(1); review labels for compliance with food allergen labeling requirements	77,500	1	77,500	1	77,500
403(w)(1); redesign labels to comply with food allergen labeling requirements	1	1	1	16	16
Total					77,516

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

A. Third-Party Disclosure

The labeling requirements of section 403(w)(1) of the FD&C Act apply to all packaged foods sold in the United States that are regulated under the FD&C Act, including both domestically manufactured and imported foods. As noted, section 403(w)(1) of the FD&C Act requires that the label of a food product declare the presence of each major food allergen. We estimate the information collection burden of the third-party disclosure associated with food allergen labeling under section 403(w)(1) of the FD&C Act as the time needed for a manufacturer to review the labels of new or reformulated products for compliance with the requirements of section 403(w)(1) of the FD&C Act and the time needed to make any needed modifications to the labels of those products. The allergen information disclosed on the label or labeling of a food product benefits consumers who purchase that food product. Because even small exposure to a food allergen can potentially cause an adverse reaction, consumers use food labeling information to help determine their product choices.

Based on a review of the information collection since our last request for OMB approval, we are decreasing our burden estimate for the redesign of labels. FALCPA was enacted in 2004, and we issued associated Agency guidance in 2015. Firms have had substantial time to redesign their labels for compliance with section 403(w) of the FD&C Act. We do not anticipate any firms needing to redesign their label to come into compliance with section 403(w)(1) of the FD&C Act. Thus, we are decreasing the number of respondents redesigning their label from 3,875 to 1 and the number of hours from 62,000 to 16. We estimate one respondent for the purpose of maintaining this information collection provision.

Table 2.--Estimated Annual Reporting Burden¹

FD&C Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
403(w)(6); petition for exemption	5	1	5	100	500
403(w)(7); notification	5	1	5	68	340
Total					840

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

B. Reporting

Under sections 403(w)(6) and (7) of the FD&C Act, respondents may request from us a determination that an ingredient is exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. An ingredient may obtain an exemption through submission and approval of a petition containing scientific evidence that demonstrates that the ingredient “does not cause an allergic response that poses a risk to human health” (section 403(w)(6) of the FD&C Act). This section also states that “the burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.” Alternately, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient “does not contain allergenic protein” or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act that the ingredient “does not cause an allergic response that poses a risk to human health” (section 403(w)(7) of the FD&C Act).

We issued a guidance document entitled “Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications,” which is available on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications>. The guidance sets forth our recommendations with regard to the information that respondents should submit in such a petition or notification. The guidance states that to evaluate these petitions and notifications, we will consider scientific evidence that describes: (1) the identity or composition of the ingredient; (2) the methods used to produce the ingredient; (3) the methods used to characterize the ingredient; (4) the intended use of the ingredient in food; and (5) either (a) for a petition, data and information, including the expected level of consumer exposure to the ingredient, that demonstrate that the ingredient, when manufactured and used as described, does not cause an allergic response that poses a risk to human health; or (b) for a notification, data, and information that demonstrate that the ingredient, when manufactured as described, does not contain allergenic

protein, or documentation of a previous determination under a process under section 409 of the FD&C Act that the ingredient does not cause an allergic response that poses a risk to human health. We use the information submitted in the petition or notification to determine whether the ingredient satisfies the criteria of section 403(w)(6) and (7) of the FD&C Act for granting the exemption.

Dated: March 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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